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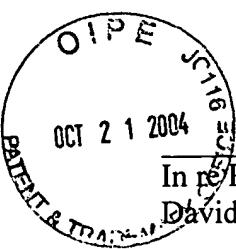
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1654 R

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Dated: _____

Docket No.: 01946/100D864-US1
(PATENT)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
David Gschneidner et al.

Application No.: 09/762,067

Confirmation No.: 7883

Filed: August 3, 2001

Art Unit: 1654

For: COMPOUNDS AND COMPOSITIONS FOR
DELIVERING ACTIVE AGENTS

Examiner: Maury Audet

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed more than three months after the U.S. filing date, OR more than three months after the date of entry of the national stage of a PCT application, AND after the mailing date of the first Office Action on the merits, whichever occurs first, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

A copy of each document on the PTO/SB/08 is attached.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as

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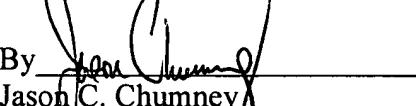
defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Our check in the amount of \$180.00 covering the fee set forth in 37 CFR 1.17(p) is enclosed. The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: October 21, 2004

Respectfully submitted,

By 
Jason C. Chumney
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Attorneys/Agents For Applicant



Application No. (if known): 09/762,067

Attorney Docket No.: 01946/100D864-US1

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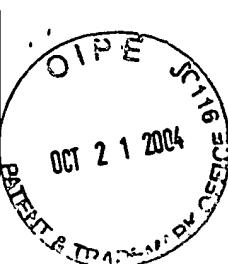
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Fee Transmittal for FY 2005 (1 page);
Information Disclosure Statement (2 pages);
List of References (PTO\SB08a\b form) (3 pages);
89 References
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FEE TRANSMITTAL

for FY 2005

Effective 10/01/2004. Patent fees are subject to annual revision.

 Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$ 180.00)**Complete if Known**

Application Number	09/762,067
Filing Date	August 3, 2001
First Named Inventor	David Gschneidner et al.
Examiner Name	Maury Audet
Art Unit	1654
Attorney Docket No.	01946/100D864-US1

METHOD OF PAYMENT (check all that apply)

Check Credit Card Money Order Other None

 Deposit Account:Deposit Account Number **04-0100**Deposit Account Name **Darby & Darby P.C.**

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FEE CALCULATION (continued)**3. ADDITIONAL FEES**

Large Entity	Small Entity	Fee Description		Fee Paid
Fee Code (\$)	Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge – late filing fee or oath		
1052 50	2052 25	Surcharge – late provisional filing fee or cover sheet.		
1053 130	1053 130	Non-English specification		
1812 2,520	1812 2,520	For filing a request for ex parte reexamination		
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action		
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action		
1251 110	2251 55	Extension for reply within first month		
1252 430	2252 215	Extension for reply within second month		
1253 980	2253 490	Extension for reply within third month		
1254 1,530	2254 765	Extension for reply within fourth month		
1255 2,080	2255 1,040	Extension for reply within fifth month		
1401 340	2401 170	Notice of Appeal		
1402 340	2402 170	Filing a brief in support of an appeal		
1403 300	2403 150	Request for oral hearing		
1451 1,510	1451 1,510	Petition to institute a public use proceeding		
1452 110	2452 55	Petition to revive – unavoidable		
1453 1,370	2453 685	Petition to revive - unintentional		
1501 1,370	2501 685	Utility issue fee (or reissue)		
1502 490	2502 245	Design issue fee		
1503 660	2503 330	Plant issue fee		
1460 130	1460 130	Petitions to the Commissioner		
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)		
1806 180	1806 180	Submission of Information Disclosure Stmt		180.00
8021 40	8021 40	Recording each patent assignment per property (times number of properties)		
1809 790	2809 395	Filing a submission after final rejection (37 CFR 1.129(a))		
1810 790	2810 395	For each additional invention to be examined (37 CFR 1.129(b))		
1801 790	2801 395	Request for Continued Examination (RCE)		
1802 900	1802 900	Request for expedited examination of a design application		
Other fee (specify)				

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ 180.00)

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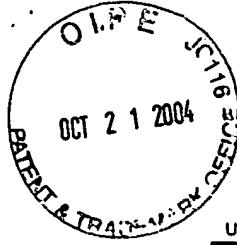
SUBMITTED BY

(Complete if applicable)

Name (Print/Type)	Jason C. Chumney	Registration No. (Attorney/Agent)	54,781	Telephone	(212) 527-7700
Signature				Date	October 21, 2004

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PTO/SB/08A (10-01)

Approved for use through 10/31/2002, OMB 0651-0031

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO				<i>Complete if Known</i>	
				Application Number	09/762,067
				Filing Date	August 6, 1999
				First Named Inventor	David Gschneidner et al.
				Art Unit	1654
				Examiner Name	Maury Audet
Sheet	1	of	3	Attorney Docket Number	01946/100D864-US1

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Memorandum
		Number-Kind Code ² (if known)			
1		6,699,467	03/2/2004	Leone-Bay, et al.	
2		6,693,208	02/17/2004	Gschneidner, et al.	
3		6,693,073	02/17/2004	Milstein, et al	
4		6,663,887	12/16/2003	Leone-Bay, et al.	
5		6,646,162	11/11/2003	Tang, et al.	
6		6,642,411	11/04/2003	Leone-Bay, et al.	
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8		6,623,731	09/23/2003	Leone-Bay, et al.	
9		6,610,329	08/26/2003	Santiago, et al.	
10		6,525,020	02/25/2003	Leone-Bay, et al.	
11		6,461,643	10/08/2002	Milstein, et al.	
12		6,440,929	08/27/2002	Milstein, et al.	
13		6,428,780	08/06/2002	Leone-Bay, et al.	
14		6,399,798	06/04/2002	Gschneidner, et al.	
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16		6,384,278	05/07/2002	Tang, et al.	
17		6,358,504	03/19/2002	Leone-Bay, et al.	
18		6,348,207	02/19/2002	Milstein, et al.	Certificate of Correction
19		6,346,242	02/12/2002	Leone-Bay, et al.	Certificate of Correction
20		6,344,213	02/05/2002	Leone-Bay, et al.	
21		6,313,088	11/06/2001	Leone-Bay, et al.	
22		6,245,359	06/12/2001	Milstein, et al.	Certificate of Correction
23		6,242,495	06/05/2001	Leone-Bay, et al.	
24		4,927,928	05/22/1990	Shroot, et al.	
25		4,900,730	02/13/1990	Miyauchi	
26		4,835,312	05/30/1989	Itoh, et al.	
27		US 2002-0001591	01/03/2002	Santiago, et al.	
28		US 2002-0120009	08/29/2002	Leone-Bay, et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)			
	29	WO99/29705	06/17/1999	Glycomed Inc.	
	30	WO98/50341	11/12/1998	Emisphere Technologies, Inc.	
	31	WO98/25589	06/18/1998	Emisphere Technologies, Inc.	
	32	WO97/47270	12/18/1997	Arad, Dorit	
	33	WO97/10197	03/20/1997	Emisphere Technologies, Inc.	
	34	WO95/28838	11/02/1995	Emisphere Technologies, Inc.	
	35	WO95/28920	11/02/1995	Emisphere Technologies, Inc.	

(W:\01946\1 00d864.us1)	DATE CONSIDERED:	
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PTO/SB/08A (10-01)

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U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
Sheet	2	of	3	Application Number	09/762,067
				Filing Date	August 6, 1999
				First Named Inventor	David Gschneidner et al.
				Art Unit	1654
				Examiner Name	Maury Audet
				Attorney Docket Number	01946/100D864-US1

36	WO03/057650	07/17/2003	Emisphere Technologies, Inc.		
37	WO03/057170	07/17/2003	Emisphere Technologies, Inc.		
38	WO03/045306	06/05/2003	Emisphere Technologies, Inc.		
39	WO03/026582	04/03/2003	Emisphere Technologies, Inc.		
40	WO02/19969	03/14/2002	Emisphere Technologies, Inc.		
41	WO02/100338	12/19/2002	Emisphere Technologies, Inc.		
42	WO02/070438	09/12/2002	Emisphere Technologies, Inc.		
43	WO02/069937	09/12/2002	Emisphere Technologies, Inc.		
44	WO01/92206	12/06/2001	Emisphere Technologies, Inc.		
45	WO01/70219	09/27/2001	Emisphere Technologies, Inc.		
46	WO01/51454	07/19/2001	Emisphere Technologies, Inc.		
47	WO01/44199	06/21/2001	Emisphere Technologies, Inc.		
48	WO01/32596	05/10/2001	Emisphere Technologies, Inc.		
49	WO01/32130	05/10/2001	Emisphere Technologies, Inc.		
50	WO00/59863	10/12/2000	Emisphere Technologies, Inc.		
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52	WO00/50386	08/31/2000	Emisphere Technologies, Inc.		
53	WO00/48589	08/24/2000	Emisphere Technologies, Inc.		
54	WO00/46182	08/10/2000	Emisphere Technologies, Inc.		
55	WO00/40203	07/13/2000	Emisphere Technologies, Inc. And Virginia Commonwealth University		
56	WO00/07979	02/17/2000	Emisphere Technologies, Inc.		
57	WO00/06534	02/10/2000	Emisphere Technologies, Inc.		
58	WO00/06184	02/10/2000	Emisphere Technologies, Inc.		
59	JP2239980	09/21/1990	Fuji Film Company, Ltd.	(Abs)	
60	FR985.340	11/02/1966	Francia Farmaceutica		
61	EP576941	06/19/1993	Nissin Flour Milling Co.		
62	EP226223	06/27/1987	Warner Lambert Co.		
63	EP05-17211	09/12/1992	Teikoku Seiyaku Kabushiki		
64	EP00/36145	09/23/1981	Inter, Research Corp.		
65	EP00/07979	05/18/2000	Dynamit Nobel AKtiengesellschaft		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

¹ Applicant's unique citation designation number (optional). ² See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
66	LEONE-BAY, A. "Microsphere Formation in a Series of Derivatized Alpha-Amino Acids: Properties, Molecular Modeling, and Oral Delivery of Salmon Calcitonin"; Journal of Medicinal Chemistry vol 38, 4257-4262 (1995)		
67	ANDREA LEONE-BAY "4-(4-Salicyloylaminophenyl)butyric Acid as a Novel Oral Delivery Agent for Recombinant Human Growth Hormone" Medi 006, Presented at the American Chemical Society, (March 1996) New Orleans, LA		
68	HO KOC-KAN; et al. " Solution Phase Preparation of Highly Pure Amide Mixtures Via In-Situ Chlorotrimethylsilane Protection and Activation" Synthetic Communication, vol. 27, no. 5: 883-895 (1997)		

{W:\01946\1 00d864us1}	DATE CONSIDERED:	
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PTO/SB/08A (10-01)

Approved for use through 10/31/2002, OMB 0651-0031

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
Sheet	3	of	3	Application Number	09/762,067
				Filing Date	August 6, 1999
				First Named Inventor	David Gschneidner et al.
				Art Unit	1654
				Examiner Name	Maury Audet
				Attorney Docket Number	01946/100D864-US1

69	LEONE-BAY, A. "Synthesis And Evaluation Of Compounds That Facilitate The Gastrointestinal Absorption Of Heparin"; Journal of Medicinal Chemistry vol 41, 1163-1171 (1998)	
70	PICCIOLA G.: "Synthesis Of Quinazolinone And Benzoazainone Acids And Study Of Their Anti-Inflammatory Properties" IT, II Farmaco, Ed. Sc. vol 31, no. 9 pgs 655-664 - English Translation (1976)	Abs
71	PICCIOLA G.: "Synthesis Of Quinazolinone And Benzoazainone Acids And Study Of Their Anti-Inflammatory Properties" Chem Abstract 86:S402t (1977)	.
72	PALAGIANO, F., ET AL. "Synthesis, Stability And Anticonvulsant Activity Of Two New GABA Prodrugs" Pharmazie 52(4): 272-276 (1997)	
73	Chem Abstract 73548-12-6	
74	Chem Abstract 70204-54-5 (04/1991)	
75	Johansen, Marianne, et al. "The Kinetics of Decompn. Of Various N-Mannich Bases of Salicylamide" Int. J. Pharm. (1980), 7(2): 119-27 (1980)	
76	Rivera, Theresa M. et al. "Oral Delivery Of Heparin In Combination With Sodium n N-[8-2-Hydroxybenzoyl] Amino]Caprylate: Pharmacological Considerations" Pharmaceutical Research, Vol. 14(12) 1830-1834 (1997)	
77	Andrea Leone-Bay "4-(4-Salicyloylaminophenyl)Butyric Acid as a Novel Oral Delivery Agent For Recombinant Human Growth Hormone" Medi 006, Presented at the American Chemical Society, March 24-28, 1997 New Orleans, LA.	
78	Leone-Bay, A.. et al. "The Evolution of an Oral Heparin Dosing Solution" Drugs of the Future Vol. 22(8) 885-891 (1997)	
79	Brayden, D. et al. "Heparin Absorption Across The Intestine: Effects of Sodium N-[8-2 Hydorxybenzoyl] Amino] Caprylate In rat in situ Intestinal Instillations Ind In Caco-2 Monolayers" Pharmaceutical Research Vol 14(2) 1772-1779 (1997)	
80	Leone-Bay, a. "Acylated Non-Alpha-Amino Acids As Novic Agents For The Oral Delivery Of Heparin Sodium, USP" Journal of Controlled Release 50: 41-49 (1998)	
81	Leone-Bay, A. "4-[4-[(2-Hydorxybenzoyl)Amino]Phenyl]Butyric Acid as a Novel Oral Delivery Agent for Recombinant Human Growth Hormone"; Journal of Medicinal Chemistry Vol 39, 2571-2578 (1996)	
82	Leone-Bay, A. "N-Acylated Alpha-Amino Acids As Novel Oral Delivery Agents For Proteins" ; Journal of Medicinal Chemistry Vol. 38, 4263-4269 (1995)	
83	Ho Koc-Kan, et al. "A Practical Synthesis Of -Aminoalkanoic Acid Derivatives Form Cycloalkanones" Synthetic Communication, Vol. 26, No. 14:2641-2649 (1996)	
84	Gurrieri and Siracusa: "Thermal Condensation of Some Alpha-Aminoacids With Phthalic Acid" Thermochimica Acta, 7 (1973) 231-239.	
85	Brown, G. and Foubister, A.J. "Receptor Bindin Sites Of Hypoglycemic Sulfonylureas and Related (Acylamino)Alkyl-[-] Benzoic Acids Jmed Chem 27, 79-81 1984	
86	Chem Abstract 70(25) pp 311 (1969)	
87	Chemical Abstract, Vol. 99(23) Abst. No. 191473I (1983)	
88	Emisphere Technologies Poster Presentation, "Oral Delivery of Human Insulin In Diabetic Rats Using Novel Delivery Agents", Monica Carozza, et al. Nov. 16-19, 1998.	
89	Amino Yusuke et al. Chem Pharm Bull 36 pgs. 4426-4434 (1988).	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language translation is attached.

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